



**SUPPLEMENTAL INFORMATION
DISCLOSURE
STATEMENT BY APPLICANT
Form PTO-1449**

ATTY. DOCKET NO.
12961/46102

APPLICATION NO.
10/766,263

APPLICANT
Z.C. TUCKER

FILING DATE
January 27, 2004

GROUP
1624

U. S. PATENT DOCUMENTS*

EXAMINER INITIAL	PATENT/PUBLICATION NUMBER	PATENT/PUBLICATION DATE	NAME	CLASS	SUBCLASS	FILING DATE*
ET	2003/0152624	August 14, 2003	Aldrich et al.	_____	_____	
ET	2003/0158176	August 21, 2003	Richards et al.	_____	_____	
ET	2004/064821	April 1, 2004	Rousselle	_____	_____	
	3,316,841	July 19, 1966	Zemitz	_____	_____	
ET	6,310,248	October 30, 2001	Andersson et al.	_____	_____	
ET	6,566,537	May 20, 2003	Andersson et al.	_____	_____	
ET	6,689,916	February 10, 2004	Andersson et al.	_____	_____	

*- copies of U.S. references are not enclosed

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
ET	766,207	December 22, 1952	DE	_____	_____	YES	
ET	831,799	June 7, 1996	EP	_____	_____		
ET	872,233	April 14, 1997	EP	_____	_____		
ET	948,321	December 10, 1997	EP	_____	_____		NO
ET	957,073	May 12, 1998	EP	_____	_____		
ET	1,025,041	February 24, 1964	GB	_____	_____		
ET	WO 02/089773	November 14, 2002	PCT	_____	_____		
ET	WO 02/11702	February 14, 2002	PCT	_____	_____		
ET	WO 03/002059	January 9, 2003	PCT	_____	_____		
ET	WO 03/007918	January 30, 2003	PCT	_____	_____		
ET	WO 03/020241	March 13, 2003	PCT	_____	_____		
ET	WO 03/026564	April 3, 2003	PCT	_____	_____		
ET	WO 03/035599	May 1, 2003	PCT	_____	_____		
ET	WO 03/039464	May 15, 2003	PCT	_____	_____		
ET	WO 03/063834	August 7, 2003	PCT	_____	_____		
ET	WO 03/099268	December 4, 2003	PCT	_____	_____		NO
ET	WO 03/103637	December 18, 2003	PCT	_____	_____		
ET	WO 03/106421	December 24, 2003	PCT	_____	_____		
ET	WO 04/019892	March 11, 2004	PCT	_____	_____		
ET	WO 98/43942	October 8, 1998	PCT	_____	_____		
ET	WO 98/56359	December 17, 1998	PCT	_____	_____		NO
ET	WO 99/58478	November 18, 1999	PCT	_____	_____		

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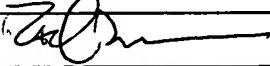
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Page 1 DATE

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OTHER DOCUMENTS

EXAMINER INITIAL		AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
ZT		Lipinski, et al., "Experimental and computational approaches to estimate solubility and permeability in drug discovery and development settings" Elsevier Advanced Drug Delivery Reviews Vol. 23, pp. 3-25, 1997
ZT		Netzer, et al., "Screening lead compounds for QT interval prolongation" Drug Discovery Today Vol. 6, No. 2, pp.78-84, January 2001
ZT		Nilvebrant & Sparf, "Differences between Binding Affinities of some Antimuscarinic Drugs in the parotid Gland and those in the Urinary Bladder and Ileum" Acta Pharmacol. et toxicol. Vol. 53, No. 4, pp. 304-313, October 1983
ZT		Pharmacology/Toxicology Review from Application Number 21-518, Center for Drug Evaluation and Research, pp. 1-3. (2004)
ZT		Roy, et al., "HERG, a Primary Human Ventricular Target of the Nonsedating Antihistamine Terfenadine" Circulation Vol. 94, No. 4, pp. 817-823, August 15, 1996

EXAM INER		DATE CONSIDERED 12 JULY 2006
EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		



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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT Form PTO-1449	ATTY. DOCKET NO. 12961/46102	APPLICATION NO. 10/766,263
	APPLICANT Z.C. TUCKER	
	FILING DATE January 27, 2004	GROUP 1624

U. S. PATENT DOCUMENTS*

EXAMINER INITIAL	PATENT/PUBLICATION NUMBER	PATENT/PUBLICATION DATE	NAME	CLASS	SUBCLASS	FILING DATE*
ZT	3,446,901	May 27, 1969	G. J. Macclesfield	_____	_____	
ZT	4,988,730	January 29, 1991	Korbonits et al.	_____	_____	
ZT	5,382,600	January 17, 1995	Jonsson et al.	_____	_____	
ZT	5,559,269	September 24, 1996	Johansson et al.	_____	_____	
ZT	5,922,914	July 13, 1999	Gage et al.	_____	_____	
ZT	6,517,864	February 11, 2003	Orup Jacobsen et al.	_____	_____	
ZT	6,630,162	October 7, 2003	Nilvebrant et al.	_____	_____	
ZT	6,713,464	March 30, 2004	Meese et al.	_____	_____	
ZT	6,770,295	August 3, 2004	Kreilgard et al.	_____	_____	
ZT	6,783,769	August 31, 2004	Arth et al.	_____	_____	
ZT	6,809,214	October 26, 2004	Meese	_____	_____	
ZT	6,809,225	October 26, 2004	Donsbach et al.	_____	_____	
ZT	6,858,650	February 22, 2005	Meese	_____	_____	
ZT	6,890,920	May 10, 2005	Richards et al.	_____	_____	
ZT	6,911,217	June 28, 2005	Gren et al.	_____	_____	
ZT	2003/0124179	July 3, 2003	Jacobsen, Lene O. et al.	_____	_____	
ZT	2004/0186061	September 23, 2004	Meese, Claus et al.	_____	_____	
ZT	2005/0004223	January 6, 2005	Slatter, John G. et al.	_____	_____	

* - copies of U.S. references are not enclosed

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
ZT	925 468 (in German, with English translation)	March 21, 1955	DE	_____	_____	YES	
ZT	1 216 318 (in German, with English translation)	May 12, 1966	DE	_____	_____	YES	
ZT	325 571	July 26, 1989	EP	_____	_____		
ZT	667 852	August 23, 1995	EP	_____	_____		
ZT	1 019 358	July 19, 2000	EP	_____	_____		
ZT	1 077 912	February 28, 2001	EP	_____	_____		
ZT	1 128 819	September 05, 2001	EP	_____	_____		
ZT	624 117	May 27, 1949	GB	_____	_____		
ZT	627 139	July 29, 1949	GB	_____	_____		
ZT	WO 93/23025	November 25, 1993	PCT	_____	_____		
ZT	WO 96/12477	May 02, 1996	PCT	_____	_____		

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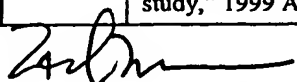
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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
ZT	WO 98/03067	January 29, 1998	PCT			
ZT	WO 00/12069	March 09, 2000	PCT			
ZT	WO 00/27364	May 18, 2000	PCT			
ZT	WO 01/34139	May 17, 2001	PCT			

OTHER DOCUMENTS

EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
ZT	Abrams et al., "Tolterodine, a new antimuscarinic agent: as effective but better tolerated than oxybutynin in patients with an overactive bladder," 1998, Br. J. Urol. 81:801-810
ZT	Anderson et al., "Once daily controlled versus immediate release oxybutynin chloride for urge urinary incontinence," 1999, J. Urol. 161:1809-1812
	Andersson et al., "Pharmacological treatment of urinary incontinence," in Abrams P., Khoury S., Wein A. (Eds), <u>Incontinence, 2nd International Consultation on Incontinence</u> , Plymouth, Plymbridge Distributors Ltd, UK, Plymouth, 2002, pp 479-511
ZT	Andersson, "Antimuscarinics for treatment of overactive bladder," 2004, Lancet Neurol. 3:46-53
ZT	Andersson & Wein, "Pharmacology of the lower urinary tract: basis for current and future treatments of urinary incontinence," 2004, Pharmacol. Rev. 56:581-631
ZT	Appell et al., "Prospective randomized controlled trial of extended release oxybutynin chloride and tolterodine tartrate in the treatment of overactive bladder: results of the OBJECT study," 2001, Mayo Clinic Proceedings 76:358-363
ZT	Breidenbach et al., "Pharmacodynamic profiling of the novel antimuscarinic drug fesoterodine on rat bladder," 2002, Proceedings of the International Continence Society, 32:449
ZT	Brynne et al., "Influence of CYP2D6 polymorphism on the pharmacokinetics and pharmacodynamics of tolterodine, 1998, Clin. Pharmacol. Thera. 63:529-539
ZT	Brynne et al., "Tolterodine does not affect the human in vivo metabolism of the probe drugs caffeine, debrisoquine, and omeprazole," 1999, Br. J. Clin. Pharmacol. 47:145-150
ZT	Brynne et al., "Fluoxetine inhibits the metabolism of tolterodine - pharmacokinetic implications and proposed clinical relevance," 1999, Br. J. Clin. Pharmacol. 48:553-563
ZT	Brynne et al., "Ketoconazole inhibits the metabolism of tolterodine in subjects with deficient CYP2D6 activity," 1999, Br. J. Clin. Pharmacol. 48:564-572
ZT	Cawello et al., "Multiple dose pharmacokinetics of fesoterodine in human subjects," 2002, Naunyn-Schmiedeberg's Arch. Pharmacol. 365 (Suppl. 1):428, 2002
ZT	Chancellor et al., "A comparison of the effects on saliva output of oxybutynin chloride and tolterodine tartrate," 2001, Clinical Therapeutics 23:753-760
ZT	Chapple & Udo, "Delay to maximum effect in overactive bladder patients treated with oxybutynin or tolterodine," 2000, European Urology 37(Suppl. 2):84, abstract 335 from the XVth Congress of the European Association of Urology, Brussels, Belgium, April 12-15, 2000
ZT	Chapple et al., "Fesoterodine a new effective and well-tolerated antimuscarinic for the treatment of urgency-frequency syndrome: results of a Phase II controlled study," 2004, Proceedings of the International Continence Society, 34:142
ZT	Clemett & Jarvis, "Tolterodine: a review of its use in the treatment of overactive bladder," 2001, Drugs & Aging 18:277-304
ZT	Cole, "Fesoterodine, an advanced antimuscarinic for the treatment of overactive bladder: A safety update," 2004, Drugs of the Future 29:715-720
ZT	Detrol® package insert, Pharmacia & Upjohn Co., April, 2004
ZT	Diokno et al., "Tolterodine (Detrol®) improves incontinence and nocturia in urological based study," 1999 April, J. Urol. 161 (4 Suppl):256, abstract 987

EXAMINER



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DATE

12 JULY 2006

EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
Zr	Ekstrom et al., "Effects of tolterodine on bladder function in healthy volunteers," Journal of Urology 153(Suppl.):394A, abstract 662 from the 19 th Annual Meeting of the American Urological Association, Las Vegas, April 23-28, 1995
Zr	Gillberg et al., "Tolterodine, a new agent with tissue effect selectivity for urinary bladder," 1994, Neurourology and Urodynamics 13:435-436, abstract 60B from International Continence Society 24 th Annual Meeting, Prague, Czech Republic, August 1994
Zr	Gillberg et al., "Comparison of the in vitro and in vivo profiles of tolterodine with those of subtype-selective muscarinic receptor antagonists," 1998, European Journal of Pharmacology 349: 285-292
Zr	Hills et al., "Tolterodine," 1998, Drugs 55:813-820
Zr	Jonas et al., "Efficacy and safety of two doses of tolterodine versus placebo in patients with detrusor overactivity and symptoms of frequency, urge incontinence, and urgency: urodynamic evaluation," 1997, World J. Urol. 15:144-151
Zr	Kershen & Hsieh, "Preview of new drugs for overactive bladder and incontinence: darifenacin, solifenacin, trospium, and duloxetine," Curr. Urol. Rep. 5:359-367
Zr	Klosa, "Eine Neue Synthese von Diphenylisopropylaminen," 1966, Journal für Praktische Chemie 4:335-340 (in German, with English translation)
Zr	Larsson et al., "Tolterodine in the treatment of overactive bladder: analysis of the pooled phase II safety and efficacy data," 1999, Urology 53: 990-998
Zr	Millard et al., "Clinical efficacy and safety of tolterodine compared to placebo in detrusor overactivity," 1999, J. Urol. 161:1551-1555
Zr	Modiri et al., "Effect of muscarinic antagonists on micturition pressure measured by cystometry in normal, conscious rats," 2002, Urology 59:963-968
Zr	Naerger et al., "Effect of tolterodine on electrically induced contractions of isolated human detrusor muscle from stable and unstable bladders," 1995, Neurourology and Urodynamics 14:524-526, abstract 76 from International Continence Society 25 th Annual Meeting, Sydney, Australia, October 1995
Zr	Nilsson et al., "Comparison of a 10 mg controlled release oxybutynin tablet with a 5 mg oxybutynin tablet in urge incontinence patients," 1997, Neurourol. Urodyn. 16:533-542
Zr	Nilvebrant & Sparf, "Receptor binding profiles of some selective muscarinic antagonists," 1988, European Journal of Pharmacology 151:83-96
Zr	Nilvebrant et al., "The in vitro pharmacological profile of tolterodine - a new agent for the treatment of urinary urge incontinence," 1994, Neurourology and Urodynamics 13:433-435, abstract 60A from International Continence Society 24 th Annual Meeting, Prague, Czech Republic, August 1994
Zr	Nilvebrant et al., "Tolterodine is not subtype (m1-m5) selective but exhibits functional bladder selectivity in vivo," 1996, Neurourology and Urodynamics 15:310-311, abstract 34 from the 26 th Annual Meeting of the International Continence Society, Athens, Greece, August 27-30, 1996
Zr	Nilvebrant, "Tolterodine and terodiline - different pharmacological profiles," pages 141-142, abstract 181a, from the 27 th Annual meeting of the International Continence Society, Yokohama, Japan, September 1997
Zr	Nilvebrant et al. "Tissue distribution of tolterodine and its metabolites: low penetration into the central nervous system," 2000, European Urology 37(Suppl. 2):84, abstract 333 from the XV th Congress of the European Association of Urology, Brussels, Belgium, April 12-15, 2000
Zr	Nilvebrant, "The mechanism of action of tolterodine," 2000, Reviews in Contemporary Pharmacotherapy 11:13-27
Zr	Olsson et al., "Food increases the bioavailability of tolterodine but not effective exposure," 2001, J. Clin. Pharmacol. 41:298-304
Zr	Olsson & Szamosi, "Food does not influence the pharmacokinetics of a new extended release formulation of tolterodine for once daily treatment of patients with overactive bladder," 2001, Clinical Pharmacokinetics 40:135-143
Zr	Olsson & Szamosi, "Multiple dose pharmacokinetics of a new once daily extended release formulation versus immediate release tolterodine," 2001, Clinical Pharmacokinetics 40:227-235

EXAMINER


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DATE

12 JULY 2006

EXAMINER INITIAL		AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
ZT		Rentzhog et al., "Efficacy and safety of tolterodine in patients with detrusor instability: a dose ranging study," 1998, Br. J. Urol. 81:42-48
ZT		Sachse et al., "Pharmacodynamics of multiple dose treatment with the novel antimuscarinic drug fesoterodine," 2002, Nauyn-Schmiedeberg's Arch. Pharmacol. 365 (Suppl. 1):413
ZT		Sachse et al., "Safety and pharmacokinetics of the novel bladder-selective antimuscarinic drug fesoterodine in populations of different age or gender," 2002, Proceedings of the International Continence Society, 32:441
ZT		Sachse et al., "Safety and pharmacokinetics of the novel bladder-selective antimuscarinic fesoterodine in populations of different ethnic origin," 2003, Proceedings of the International Continence Society, 33:377
ZT		Sachse et al., "Dose-proportional pharmacokinetics of the new antimuscarinic fesoterodine," 2003, Nauyn-Schmiedeberg's Arch. Pharmacol. 367 (Suppl. 1):446
ZT		Sachse et al., "Pharmacodynamics and pharmacokinetics of ascending multiple oral doses of the novel, bladder-selective antimuscarinic fesoterodine," 2003, Eur. Urol. Suppl 2:111
ZT		Sachse et al., "Concomitant food intake does not significantly influence the pharmacokinetics of the novel, bladder-selective antimuscarinic fesoterodine," 2004, Proceedings of the International Continence Society, 34:580
ZT		Sachse et al., "Safety, tolerability and pharmacokinetics of fesoterodine in patients with hepatic impairment," 2004, Proceedings of the International Continence Society, 34:585
ZT		Sachse et al., "Safety, tolerability and pharmacokinetics of fesoterodine after co-treatment with the potent cytochrome P450 3A4 inhibitor ketoconazole," 2004, Proceedings of the International Continence Society, 34:586
ZT		Sachse et al., "Clinical pharmacological aspects of the novel bladder-selective antimuscarinic fesoterodine," 2004, Progrès en Urologie, 14 (Suppl. 3):58
ZT		Stahl et al., "Urodynamic and other effects of tolterodine: a novel antimuscarinic drug for the treatment of detrusor overactivity," 1995, Neurourol. Urodyn. 14:647-55
ZT		Teuvo et al "Extended release tolterodine compared with immediate release tolterodine for the treatment of overactive bladder," 2000, European Urology 37(Suppl. 2):84, abstract 334 from the XVth Congress of the European Association of Urology, Brussels, Belgium, April 12-15, 2000
ZT		Van Kerrebroeck et al., "Tolterodine once daily: superior efficacy and tolerability in the treatment of the overactive bladder," 2001, Urology 57:414-421
ZT		Van Kerrebroeck et al., "Clinical efficacy and safety of tolterodine compared to oxybutynin in patients with overactive bladder," 1997, Neurourol. Urodyn. 16:478-479, abstract no. 91 from the 27th Annual meeting of the International Continence Society, Yokohama, Japan, September 1997
ZT		Versi et al., "Dry mouth with conventional and controlled release oxybutynin in urinary incontinence," 2000, Obstet. Gynecol. 95:718-721
ZT		Wefer et al., "Tolterodine: an overview," 2001, World Journal of Urology 19:312-318

EXAMINER		DATE CONSIDERED 12 JULY 2006
EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		